Message Text

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54
ORIGIN HEW-06

INFO OCT-01 AF-08 EUR-12 EA-09 NEA-10 ISO-00 OES-06 MED-03

COME-00 EB-07 (ISO) R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: MACODDING
EUR/EE:EWING
EA: NSILVER
NEA:EABINGTON
AF/F:DKEOUGH
---------- 129721
P 252201Z AUG 76
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY BONN PRIORITY
AMEMBASSY NEW DELHI PRIORITY
AMEMBASSY ROME PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY SEOUL PRIORITY
AMEMBASSY ISLAMABAD PRIORITY
AMEMBASSY LISBON PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY ANKARA PRIORITY
AMEMBASSY LONDON PRIORITY

UNCLAS STATE 211581

E.O. 11652: N/A TAGS: OGEN, ETRD, EIND, TBIO, AS, AU, BE,

FR, GW, TN, KS, PK, PO SF, SP, TU, UK

SUBJECT: FDA ADVISORY -DEFECTIVE IMPLANTABLE PACEMAK-
ERS (RECALL T-117/118-6)
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1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED:

T-117-6, STARR EDWARDS FIXED RATE IMPLANTABLE PACEMAKERS MODEL 8152.

T-118-6, STARR EDWARDS DEMAND IMPLANTABLE PACEMAKERS MODEL 8116.

ALL SUBJECT PACEMAKERS MANUFACTURED AND DISTRIBUTED PRIOR TO SEPTEMBER 1974 ARE INCLUDED IN THIS RECALL.

PRODUCT IDENTIFICATION:

TWO HEART PACEMAKERS CONFIGURATIONS ARE INVOLVED - FIXED RATE AND DEMAND TYPE, EACH PACER BEARS EMBOSSED LABELING WHICH READS IN PART: "STARR-EDWARDS XXX PACER XXX EDWARDS LABORATORIES, SANTA ANA, CALIFORNIA XXX:. EACH PACEMAKER IS PACKAGED IN A PLASTIC BOX LABELED IN PART: "STARR-ED-

WARDS XXX IMPLANTABLE PULSE GENERATOR XXX DO NOT AUTOCLAVE OR EXCEED 140 DEGREES F. XXX". EACH PLASTIC BOX IS PACKAGED IN A PLASTIC STRIP PACK FOR STERILIZATION. THIS PACKAGE IN TURN IS PACKAGED IN A CARDBOARD BOX WHICH IT-SELF IS PACKAGED IN ANOTHER CARDBOARD BOX WHICH IS LAB-ELED IN PART: "EDWARDS LABORATORIES DIVISION OF AMERICAN HOSPITAL SUPPLY CORPORATION, P O BOX 11150, SANTA ANA, CALIFORNIA XXX CONTAINS ONE PACEMAKER PULSE GENERATOR MODEL XXX RATE XXX SERIAL XXX USE BEFORE XXX. OTHER MISCELLAN-EOUS LABELING IS INCLUDED WITH EACH UNIT IN THE FIRST CARDBOARD CARTON. THERE ARE NO PRIVATE LABELS.

LOT NOS: ALL MODELS 8116 AND 8152 PACEMAKERS MANUFACTURED PRIOR TO SEPTEMBER 1974 ARE INVOLVED.

MANUFACTURER/RECALLING FIRM: EDWARDS PACEMAKERS SYSTEMS
DIVISION OF AMERICAN HOSPITAL SUPPLY CORPORATION
1923 S. E. MAIN STREET
IRVINE, CALIFORNIA 92714
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2. REASON FOR RECALL: ON 5/25/76, REPRESENTATIVES OF EDWARDS MET WITH REPRESENTATIVES OF THE BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS CONCERNING THE MODEL 8116 AND 8152 HEART PACEMAKERS. THE FIRM INFORMED THE BUREAU THAT EIGHT PACEMAKERS HAD BEEN RETURNED TO THEM WHICH NO LONGER PRODUCED ANY OUTPUT. THE FIRM STATED THAT THE PROBLEM INVOLVED CORROSION OF THE PACEMAKER OUTPUT PINS

SUCH THAT ELECTRICAL IMPULSES COULD NO LONGER BE DELIVERED TO THE HEART. THEY FELT THE PROBLEM OCCURRED GENERALLY WITHIN 0-4 MONTHS POST IMPLANT, HOWEVER, THEY STATED THAT THEY COULD NOT BE CERTAIN THAT PACEMAKERS IMPLANTED FOR LONGER PERIODS OF TIME COULD NOT ALSO BE SUBJECT TO THE PROBLEM. THE FIRM BELIEVED THAT THE PROBLEM OCCURRED ONLY IN PACERS MANUFACTURED PRIOR TO 9/1974 WHICH USED AN OLDER OUTPUT PIN CONFIGURATION. THE FIRM BELIEVED THE CORROSION OCCURRED FROM A COMBINATION OF THREE FACTORS, ALL OF WHICH MUST BE PRESENT: 1. THE OUTPUT PIN CONSISTING OF HAYNES 25 ALLOY IS NOT PROPERLY CLEANED PRIOR TO SEALING. 2. A CHANNEL FOR FLUID PENETRATION MUST BE PRESENT. 3. BODY FLUID MUST PENETRATE THE EPOXY SEALANT WHICH SURROUNDS THE OUTPUT PIN. THE FIRM BELIEVES THE PROBLEM IS ISOLATED TO 500 PACEMAKERS MANUFACTURED PRIOR TO 9/1974 BECAUSE UP UNTIL THAT PERIOD OF TIME, OUTPUT PINS WERE OF "L" SHAPE AND WERE SEALED WITH THE PACER

USING 2 SEPARATE EPOXY FILLS. PACEMAKERS MANUFACTURED FOLLOWING 9/1974 HAVE STRAIGHT OUTPUT PINS AND ARE SEALED USING AN EPOXY FILL. IN ADDITION, BEGINNING 9/1975 THE FIRM HAS BEGUN CLEANING THE OUTPUT ELEMENTS USING A SPECIALIZED METHOD. THE FIRMS INITIAL RECALL EFFORTS WERE DIRECTED ONLY TO THOSE UNITS WHICH THE FIRM CLAIM HAD BEEN IMPLANTED FOR UP TO 12 MONTHS. THEREFORE, ON 5/21/76 ALL PHYSICIANS MONITORING PATIENTS WITH SUSPECT PACERS (0-12 MONTHS POST IMPLANT) WERE ALERTED TO THE PACER CORROSION PROBLEM. THE ALERT WAS FOLLOWED BY TWO LETTERS, ONE LETTER WAS SENT TO PHYSICIANS MONITORING PATIENTS WITH PACERS 0-8 MONTHS IMPLANT AND THE SECOND WAS SENT TO PHYSICIANS WITH 9-12 MONTHS POST IMPLANT. THE FIRST LETTER ADVISED PHYSICIANS TO CONSIDER PROPHYLACTIC REPLACEMENT OF UNITS IN PACER DEPENDENT INDIVIDUALS. THE UNCLASSIFIED

SECOND LETTER MADE NO REFERENCE TO EXPLANATION BUT PROVIDED A COPY OF THE FIRST LETTER FOR THE PATIENTS REVIEW. ON 6/4/76 LETTERS WERE SENT TO PHYSICIANS MONITORING THE REMAINING UNITS OF THE 500 PACERS PRODUCED PRIOR TO 9/1974 AND ADVISED THEM OF THE PRESENT PACER PROBLEMS. THIS LETTER DID NOT RECOMMEND EXPLANATION BUT SIMPLY STATED THAT IT WAS LEFT TO THE PHYSICIAN TO DECIDE THE BEST COURSE OF ACTION BASED ON THE EXPLANATION PROVIDED IN THE LETTER. A PORTION OF THIS LETTER IS QUOTED AS FOLLOWS: "XXX FAILURE DATE INDICATES THE LIKELIHOOD OF FAILURE DECREASES WITH TIME. THE DESIRABILITY OF ROUTINE FOLLOW-UP, AS WITH ALL PACEMAKER PATIENTS, IS EMPHASIZED."

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL NOTIFICATIONS

ISSUED BY THE FIRM. QUESTIONS REGARDING THESE RECALLS
SHOULD BE REFERRED TO THE FIRM DIRECTLY.

4. FOREIGN CONSIGNEES AS FOLLOWS:

EDWARDS LABORATORIES
P O BOX 816
CAPETOWN, SOUTH AFRICA

DADE-GRIFOLS S.A.
JESUS Y MARIA 6
BARCELONA 6
SPAIN

EDWARDS LABORATORIES/SOUTH AFRICA
P O BOX 2726
JOHANNESBURG, SOUTH AFRICA 2000

SOC. COM. MULTIRADIX, S.A.R.L.
P O BOX 1970
LISBON 1, PORTUGAL

INTEREX COMPANY
P O BOX 7252
KARACHI-3, PAKISTAN

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SEDA, S.A.S.
VIA CARLO RAVIZZA, 34/1
20149 MILANO, ITALY

AHS/AUSTRALIA
P O BOX 4552
MELBOURNE, AUSTRALIA

AHS/FRANCE
BOITE POSTALE 7L6
95004 CERGY, FRANCE

J. MITRA & BROS. PVT. LTD.
20 DOUBLE STOREY MARKET
NEW RAJINDER NAGAR
NEW DELHI, INDIA 110060

EDWARDS LABORATORIES
ABT. DER MERZ-DADE GMBH
8000 LERCHENSTRASSE 5
MUNICH 50
WEST GERMANY

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SCIENTIFIC PRODUCTS, INC.
SANKAIDO BUILDING
9-13 AKASAKA 1-CHOME
MINATO-KU
TOKYO 107, JAPAN

COMESA K.G.
POSTFACT 75
VIENNA IX, AUSTRIA

AMERICAN HOSPITAL SUPPLY CORPORATION
INTERNATIONAL, INC. - KOREA BRANCH
P O BOX 1058
SEOUL, KOREA

PRIM, S.A.
JORGE JUAN, 141
MADRID 28, SPAIN
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CAVIT TULCA
P O BOX 525
BEYOGLU/INSTANBUL
TURKEY

EDWARDS LABORATORIES/U.K.
AMERICAN HOSPITAL SUPPLY
STATION ROAD
DIDCOT, BERKSHIRE
UNITED KINGDOM

PAUL LOUIS
DIVISION OF AHS/BELGIUM
,0, CHAUSSEE DE ZELLIK
B-1080 BRUSSELS/BELGIUM KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 25 AUG 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE211581
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760325-0925
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19760819/aaaaaqjt.tel
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Original Classification: UNCLASSIFIED
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TAGS: SWEL, AS, US, FDA
To: CANBERRA
VIENNA
MULTIPLE
Type: TE
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